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1 Introduction

This chapter gives an overview of the iSleep 20+/20i/22/25 and this service manual.

WARNING!

This product must be repaired and/or modified in accordance with Breas service manuals, technical bulletins, and any special service instructions, by service technicians that have been authorised after the Breas iSleep 20+/20i/22/25 service training, or have an equivalent technical knowledge on medical respiratory devices.

Deviation from these service instructions may lead to risk of personal injury!

1.1 About the iSleep 20+/20i/22/25 CPAP/Bi-level device

1.1.1 Function

iSleep 20+

The iSleep 20+ is a CPAP system that provides a continuous positive airway pressure. This can prevent the user's upper airways from collapsing and therefore avoid breathing problems associated with airway collapse and obstruction.

The iSleep 20+ has a pressure sensor that continuously monitors output pressure to the patient and reference ambient pressure, so that the device automatically will compensate for altitude changes.

The internal memory of the iSleep 20+ can be downloaded to a PC where you can view the patient compliance data in the Breas iSleep PC Software.

iSleep 20i

The iSleep 20i is a CPAP system that provides a continuous positive airway pressure. This can prevent the user's upper airways from collapsing and therefore avoid breathing problems associated with airway collapse and obstruction.

The pressure delivered by the iSleep 20i can be set either:

- to a constant pressure level (constant CPAP mode), or
- to permit self-adjustment in response to the patient's breathing (self adjusting intelligent CPAP mode, iMode).

The appropriate pressure for CPAP therapy often varies during sleep. In the iMode, the iSleep 20i uses an airflow sensor and an advanced signal processing technique to detect various breathing patterns and to provide the appropriate CPAP treatment.

The iSleep 20i has a pressure sensor that continuously monitors output pressure to the patient and reference ambient pressure, so that the device automatically will compensate for altitude changes.

The internal memory of the iSleep 20i can be downloaded to a PC where you can view the patient compliance data in the Breas iSleep PC Software.

iSleep 22

The iSleep 22 is a bi-level system with a CPAP function. The positive pressure can prevent the user's upper airways from collapsing and therefore avoid breathing problems associated with airway collapse and obstruction.

In bi-level mode the iSleep 22 have an adjustable inspiratory trigger and an automatically leakage adjusted expiratory trigger. The inspiratory pressure is set by the IPAP setting. The end-expiratory pressure is set by the EPAP setting.

The iSleep 22 has a pressure sensor that continuously monitors output pressure to the patient and reference ambient pressure, so that the device automatically will compensate for altitude changes.

The internal memory of the iSleep 22 can be downloaded to a PC where you can view the patient compliance data in the Breas iSleep PC Software.

iSleep 25

The iSleep 25 is a bi-level system with a CPAP function. The positive pressure can prevent the user's upper airways from collapsing and therefore avoid breathing problems associated with airway collapse and obstruction.

In bi-level mode the iSleep 25 have an adjustable inspiratory trigger and an adjustable expiratory trigger. The inspiratory pressure is set by the IPAP setting. The endexpiratory pressure is set by the EPAP setting.

The iSleep 25 has a pressure sensor that continuously monitors output pressure to the patient and reference ambient pressure, so that the device automatically will compensate for altitude changes.

The internal memory of the iSleep 25 can be downloaded to a PC where you can view the patient compliance data in the Breas iSleep PC Software

1.1.2 Intended Use

For a detailed description on intended use, refer to the iSleep 20+/20i/22/25 Clinician's or User Manuals.

1.1.3 Design

The iSleep 20+/20i/22/25 is constructed around a blower assembly.

A microprocessor controls the correct speed of the blower motor by means of calculations based on the settings and pressure. The reference ambient pressure and trigger settings (iSleep 22/25 only) are monitored at the same time.

1.1.4 Service Personnel's Training Requirements

Service personnel working with the iSleep 20+/20i/22/25 should have medical/technical training and a good knowledge of the construction and function of respiratory devices.

Always contact your Breas representative if you have any questions or if any training is required.

1.2 About this Manual

1.2.1 Scope

This manual describes all the checks and the additional service actions for the iSleep 20+/20i/22/25. The manual contains all the documentation that is required for the service of the CPAP/bi-level device, such as replacement parts lists, exploded drawings, component location guides, etc.

Breas Medical AB reserves the right to make changes to the products and/or the contents of this manual without any prior notice.

1.2.2 Intended Audience

This service manual is intended for service technicians who have medical/technical training and who have a good knowledge of the construction and function of respiratory devices.

Always contact your Breas representative if you have any questions or if any training is required.

The service manual is not intended for clinical personnel or patients, who will find all the information they need in the iSleep 20+/20i/22/25 Clinician's and User Manual.

1.2.3 Icons

In this manual, icons are used to highlight specific information. The meaning of each icon is explained in the table below.

ICON	EXPLANATION
	Warning! Risk of death and serious personal injury.
	Caution! Risk of minor or moderate injury. Risk of equipment damage, loss of data, extra work, or unexpected results.
	Note Information that may be valuable but is not of critical importance, tips.
	Reference Reference to other manuals with additional information on a specific topic.

2 Service Instructions

The iSleep 20+/20i/22/25 is designed to give users many years of trouble-free breathing assistance. The iSleep 20+/20i/22/25 requires no periodic maintenance.

This chapter describes all the checks and additional service instructions for the iSleep 20+/20i/22/25.

WARNING!

This product must be repaired and/or modified in accordance with Breas service manuals, technical bulletins, and any special service instructions, by service technicians that have been authorised after the Breas iSleep 20+/20i/22/25 service training, or have an equivalent technical knowledge on medical respiratory devices.

Deviation from these service instructions may lead to risk of personal injury!

The patient and care provider should follow the checks that are described in the iSleep 20+/20i/22/25 User and Clinician's Manual.

2.1 Introduction

Before you start a service, read the safety precautions and make sure you have a new service record and all the necessary equipment, tools, and replacement parts at hand. It is also important that any peripheral equipment is checked at the same time as the services are carried out.

2.1.1 Safety Precautions

Follow the safety precautions below when working with the iSleep 20+/20i/22/25:

- Do not work on the CPAP/bi-level device with the casing removed and the power supply connected, unless the instructions in this manual clearly says so.
- Always use caution when working with the CPAP/bi-level device connected to the mains and the casing removed.
- Do not use explosive gases and/or fluids near the CPAP/bi-level device.
- Make sure that all precautions to prevent electrostatic discharge (ESD) have been taken. Follow all regulations regarding ESD.

The iSleep 20+/20i/22/25 User and Clinician's Manuals contains extended lists of safety precautions.

2.1.2 Service Record

The Breas service record is found in chapter 9 “Appendices”.

Copy the service record and use it for noting the service checks while performing the service.

2.1.3 Inspection Equipment and Tools

Before starting the service of the iSleep 20+/20i/22/25, make sure you have the following equipment at hand:

- Pressure manometer (for example Thommen HM 28 digital manometer, Breas part no 001937).
- Torx key TX 10.
- iSleep to PC communication cable, Breas part no 003588.
- iSleep/Vivo Service Software, available for download from Breas Extranet. Contact Breas technical support for more information.

2.1.4 Replacement Parts

The following replacement parts should be available when servicing the CPAP/bi-level device:

DESCRIPTION	PART NO.
Patient air filter, grey, washable (5 pcs)	004154
Patient air filter, white, disposable (5 pcs)	004153
If required:	
Clock battery, CR 2032	002129

2.2 Preparing for Inspection

2.2.1 Initial Recording

1 Copy a new service record (see "Service Record iSleep 20+/20i/22/25" on page 44).

2 Identify the iSleep 20+/20i/22 or 25.

3 Note the model and serial number and any inventory number on the service record.

4 Check any comments recorded on the previous service records.

5 Document the current patient settings.

6 Make sure that the iSleep 20+/20i/22/25 has the latest available firmware.

The firmware version is found at the "Device information" screen. Access the "Device information" using the menu as described in the iSleep 20+/20i/22/25 Clinician's Manual.
The latest firmware is available from Breas' Extranet. Contact Breas technical support for more information.

7 Note the number of Total operating hours on the service record.

The operating hours are found at the "Device information" screen. Access the "Device information" using the menu as described in the iSleep 20+/20i/22/25 Clinician's Manual.

2.2.2 Inspecting the Markings

Make sure that all markings on the CPAP/bi-level device's information labels can be read:

- Model description, serial number
- Warning texts
- Any inventory marking
- Any other texts

2.2.3 Information from the Patient/User

Check the following with the patient:

- Has the CPAP/bi-level device functioned without any problems? If not, what were they?
- How does the patient/care provider check the function of the CPAP/bi-level device? How often?
- How often is the filter replaced?
- Other observations?

2.2.4 Validity of the Documentation

1 Check the validity of the User or Clinician's Manual enclosed with the CPAP/bi-level device.

2 Check if any modification or upgrading of the CPAP/bi-level device needs to be done at the same time as the service.

2.3 External Inspection

2.3.1 Visual Inspection for External Damage and Wear

1. Clean the outside of the CPAP/bi-level device using a mild soap solution.
2. Check for any visible damage to the casing and the other components.
3. Check that nothing has become loose.
4. Check that the rear lid is connected properly to the CPAP/bi-level device.

2.3.2 Checking the HA01 Humidifier (if used)

1. Remove and open the HA01.
2. Check that there is no visible damage.
3. Check that the water container is clean.
4. Check that the humidifier is connected properly to the CPAP/bi-level device.

2.3.3 Checking the Power Connection

1. Check the plugs on the power cord, the cord itself, and the CPAP/bi-level device's power socket.
2. Check the power supply.
3. Inspect the external battery cable, if used.

2.3.4 Inspecting the Patient Circuit

Inspect the patient circuit and replace it if necessary.

2.3.5 Inspecting the CPAP/Bi-level Device Accessories

Check any other accessories that are used with the CPAP/bi-level device.

2.3.6 Changing/Washing the Patient Filters

1. Change the white air filter (if used).
2. Change or wash the grey filter, if necessary.

2.3.7 Minimum Function Check

1. Connect the power cord.
2. Connect the patient circuit.
3. Switch on the CPAP/bi-level device and make sure it operates normally.

2.4 Internal Inspection

Perform an internal inspection if having opened the iSleep 20+/20i/22/25.

Make sure to disconnect the power supply before opening the casing of the CPAP/bi-level device.

2.4.1 Cleaning the Inside of the CPAP/Bi-level Device

1 Open the casing. See "Opening the iSleep 20+/20i/22/25 and Replacing the Main Components" on page 25 for instructions.

2 Remove any dirt or dust that has collected in the CPAP device casing.

3 Open the dark grey air channel top by pulling it straight up and remove any dirt or dust. Press the air channel back in place and make sure it fits properly.

2.4.2 Checking the Cables

Inspect all the cables and their connectors. Check the front and rear panels to make sure that the cables and the tubes are not pinched or kinked.

2.4.3 Checking the Fastening of Components

Make sure that all the components, such as the circuit board, the connectors and the tubings are securely fastened.

2.4.4 Checking the Power Supply

Make sure that the power connector is undamaged and that it is securely in place.

2.4.5 Reassembling the Casing

See "Opening the iSleep 20+/20i/22/25 and Replacing the Main Components" on page 25 for instructions.

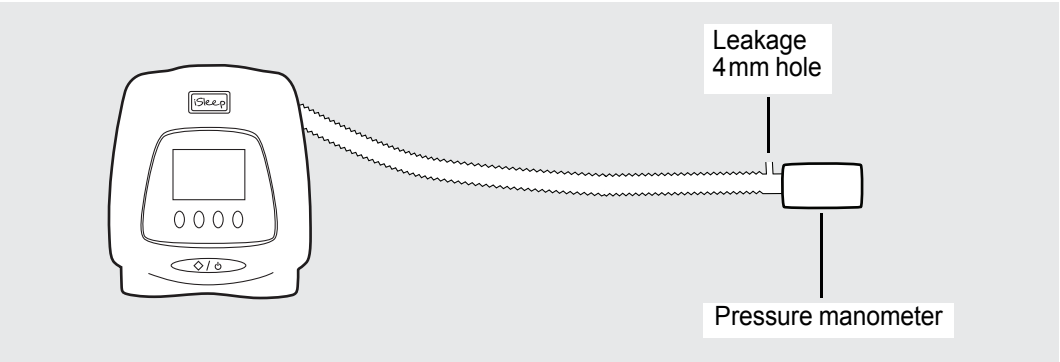
2.5 Complete Function Test

You can also perform the complete function test using the "iSleep/Vivo Service Software".

To perform a complete function test, all tasks in this section needs to be completed in the written order.

2.5.1 Checking the pressure

1 Connect a 4mm restrictor and a pressure manometer to the iSleep 20+/20i/22/25.



2 Adjust the settings as follows:

SETTING	VALUE
Mode (iSleep 20i/22/25 only)	CPAP
CPAP	4 cmH_2O
Ramp Function	Off

3 Start the iSleep 20+/20i/22/25 and let it run for 30 minutes before the test.

4 Measure and check that the measured value for each pressure is correct.

CPAP	TOLERANCE
4 cmH_2O	±0.6 cmH_2O
10 cmH_2O	±0.8 cmH_2O
15 cmH_2O	±1.0 cmH_2O
20 cmH_2O	±1.2 cmH_2O

If the measured pressure values are not within tolerance, perform a pressure calibration/adjustment of the CPAP device (see "Upgrade and Calibration" on page 30).

iSleep 25 only

5 Adjust the settings as follows:

SETTING	VALUE
Mode	Bi-Level
IPAP	25 cmH_2O
EPAP	20 cmH_2O
Backup Rate	4
Insp. Trigger	Auto
Exp. Trigger	Auto

6 Measure and check that the pressure for IPAP is correct, tolerance ±1.4 cmH_2O.

If the measured pressure values are not within tolerance, perform a pressure calibration/adjustment of the CPAP device (see "Upgrade and Calibration" on page 30).

2.5.2 Checking the Mask-Off Detection

1 Start the iSleep 20+/20i/22/25.

2 Disconnect the tube from the air outlet.

3 Wait approximately 30 seconds and check that the iSleep 20+/20i/22/25 reduces pressure and that the mask-off indication appears on the display.

4 Reconnect the tube with the 4mm leakage hole.

5 Check that the iSleep 20+/20i/22/25 delivers the set pressure.

Read more about the mask-off detection in the iSleep 20+/20i/22/25 Clinician's manual.

2.5.3 Checking the Snooze Function

1 Adjust the settings as follows:

SETTING	VALUE
Mode (iSleep 20i/22/25 only)	CPAP
CPAP	10 cmH_2O

2 Start the iSleep 20+/20i/22/25.

3 Disconnect the tube from the air outlet.

4 Shortly press the on/off button.

5 Check that the iSleep 20+/20i/22/25 delivers a low flow and that the snooze indication appears on the display.

6 Wait 15 seconds.

7 Attach the tube to the air outlet.

8 Check that the iSleep 20+/20i/22/25 inactivates the snooze function and delivers the set pressure.

9 Shortly press the on/off button so that the snooze function activates.

10 Wait approximately 10 seconds and make sure that the iSleep 20+/20i/22/25 inactivates the snooze function and delivers the set pressure.

Read more about the Snooze function in the iSleep 20+/20i/22/25 Clinician's manual.

2.5.4 Checking the Leakage Indication

11 Start the iSleep 20+/20i/22/25 and let it run for 40 seconds.

12 Check the leakage indication on the display of the iSleep 20+/20i/22/25.

	LEAKAGE	TOLERANCE
The leakage indication shall be:	25 l/min	±5 l/min

2.5.5 Checking the Power Fail Indication

1 Start the iSleep 20+/20i/22/25.

2 Disconnect the power cord from the mains.
The power fail indication shall occur within 10 seconds.
The indication can be silenced by pressing the on/off button.

3 Reconnect the power cord to the mains.

2.5.6 Checking the Backup Rate (iSleep 22/25 only)

1 Adjust the settings as follows:

SETTING	VALUE
Mode	Bi-Level
EPAP	4 cmH_2O
IPAP	10 cmH_2O
Backup Rate (iSleep 25 only)	6

2 Start the iSleep 22/25 and let it run for 2 minutes.

3 Check that the iSleep 22/25 delivers the 6 bpm backup rate.

2.5.7 Checking the Inspiratory Trigger (iSleep 22/25 only)

1 Connect a patient circuit to the iSleep 22/25.

2 Start the iSleep 22/25.

3 Create a spontaneous breath (inspiratory flow) and make sure a triggered breath is given.
The inspiratory trigger indicator **T** shall be shown on the display.

2.5.8 Adjusting the Settings for the Patient

Adjust the settings as prescribed for the patient.

2.6 Electrical Safety Precautions

Electrical safety measurements must be made in accordance with IEC 601.

Use an automatic electrical safety tester to make the measurements. All tests must be performed in accordance with class II type BF.

Supply Voltage

Note the power voltage reading.

The voltage must be noted at each service check, as the currents measured are directly in relation to the supply voltage. This allows all measurements made on the same CPAP/bi-level device to be compared with measurements made on different occasions.

Insulation

The insulation resistance is measured using a 500 V DC power supply. The most suitable method is to connect the plus lead to the two CPAP/bi-level device power socket pins, and the minus lead to the casing or the patient air connector. The measurements made during the delivery inspection can be used as reference values for measurements made during future services. If no reference values are available, the value for the insulation resistance should be >20 MΩ .

Leakage Currents

The leakage currents are measured at different parts of the CPAP/bi-level device using an RC circuit to earth.

Make the measurements partly at normal case (NC) and at the single fault condition (SFC). Reverse the polarity of the power supply and note the highest value.

Leakage currents to earth must not exceed the stated limit values.

Leakage Currents from the Casing

The leakage current of the casing is measured at an unpainted point, for example, the head of a screw.

Limit values: NC <0.1 mA

SFC <0.5 mA

Break neutral for SFC.

Patient Leakage Currents

The patient leakage current is measured between the patient connector and earth.

Limit values: NC <0.1 mA

SFC <0.5 mA

Break neutral for SFC.

Leakage Currents with Mains Power Supply at the Patient-connected Part

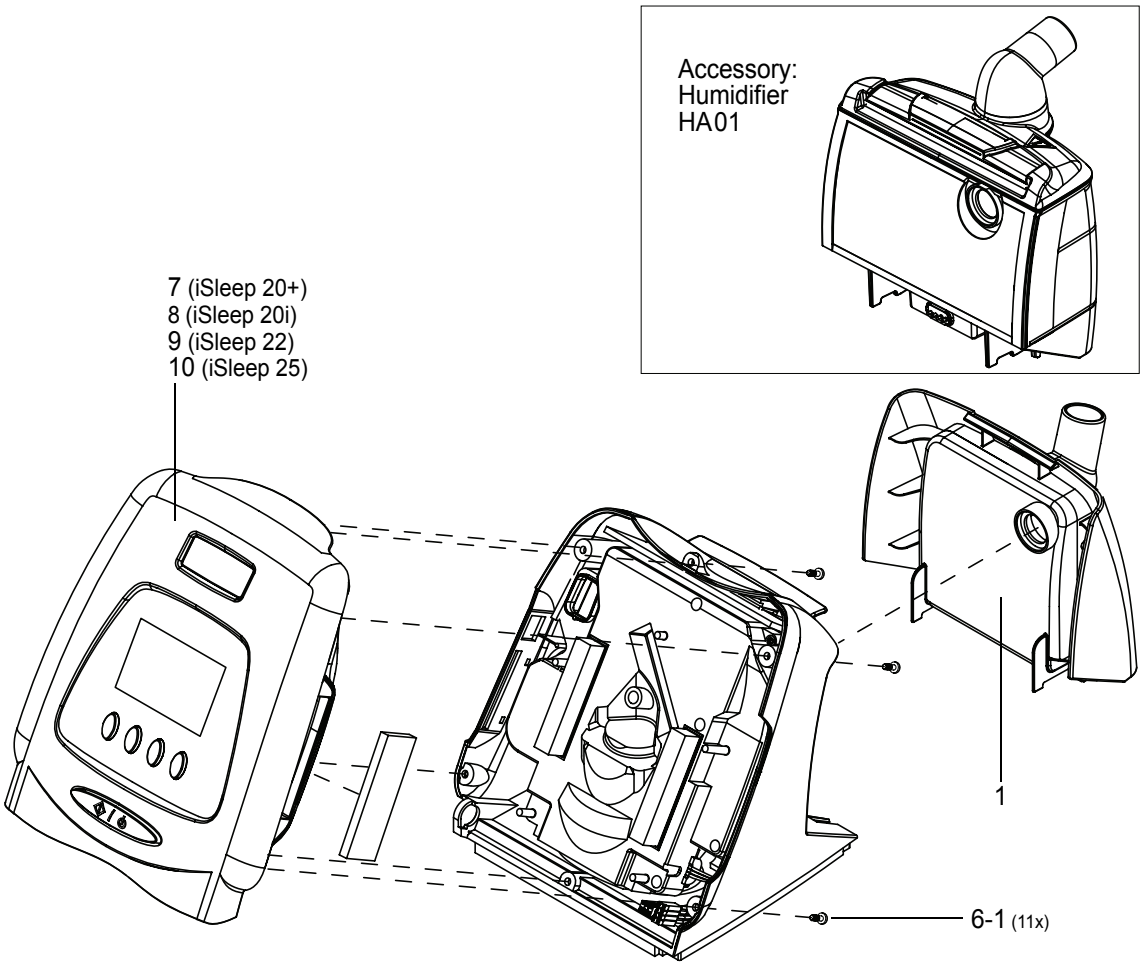
This test must be done using an automatic electrical safety tester with this function. See the safety instructions for the tester.

Limit value: SFC <5 mA

3 Parts Location

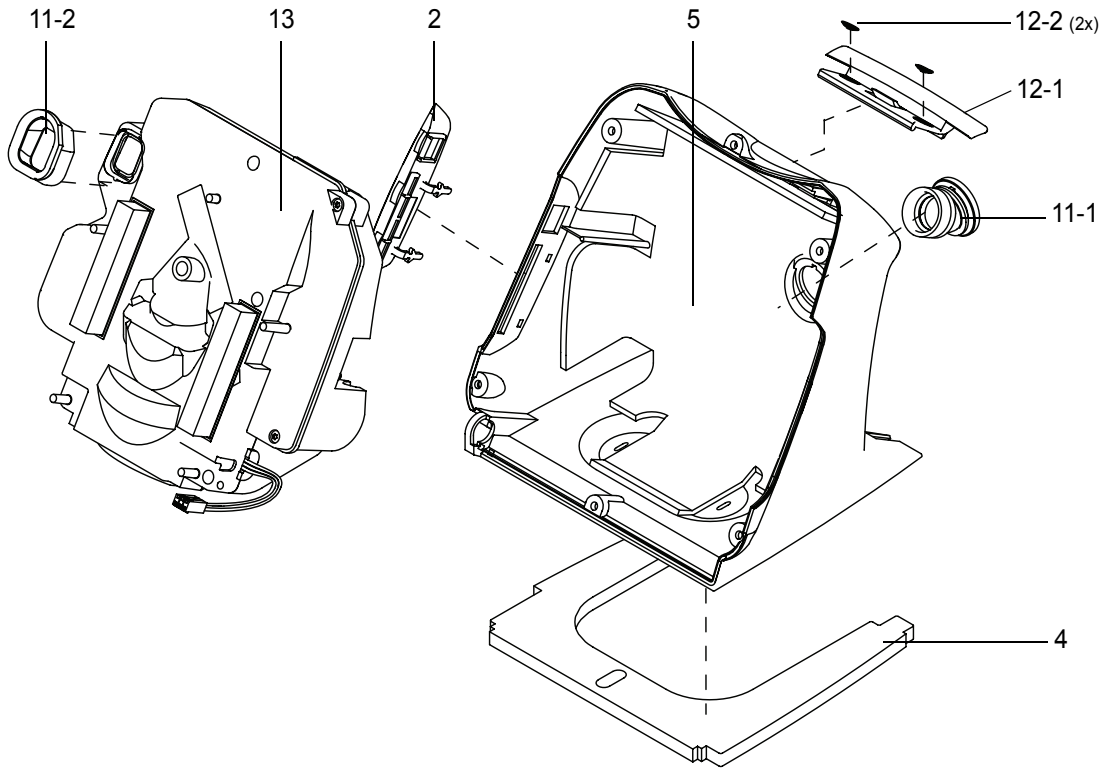
This chapter contains part-number lists and drawings of the parts for the iSleep 20+/20i/22/25.

3.1 Parts Drawing 1 – Main Components



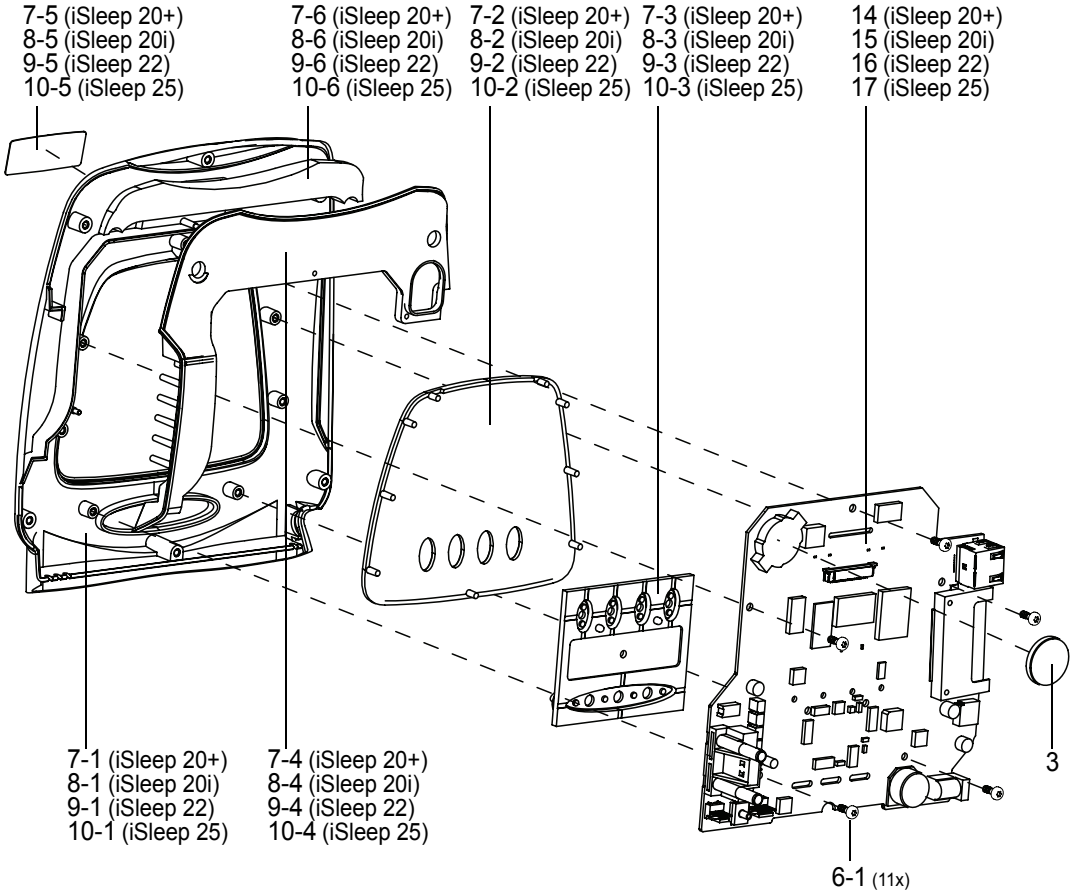
For definitions of the part numbers, refer to the parts list in section 3.5, "Parts List for the iSleep 20+/20i/22 and 25", on page 19.

3.2 Parts Drawing 2 – Back Casing, Blower Unit



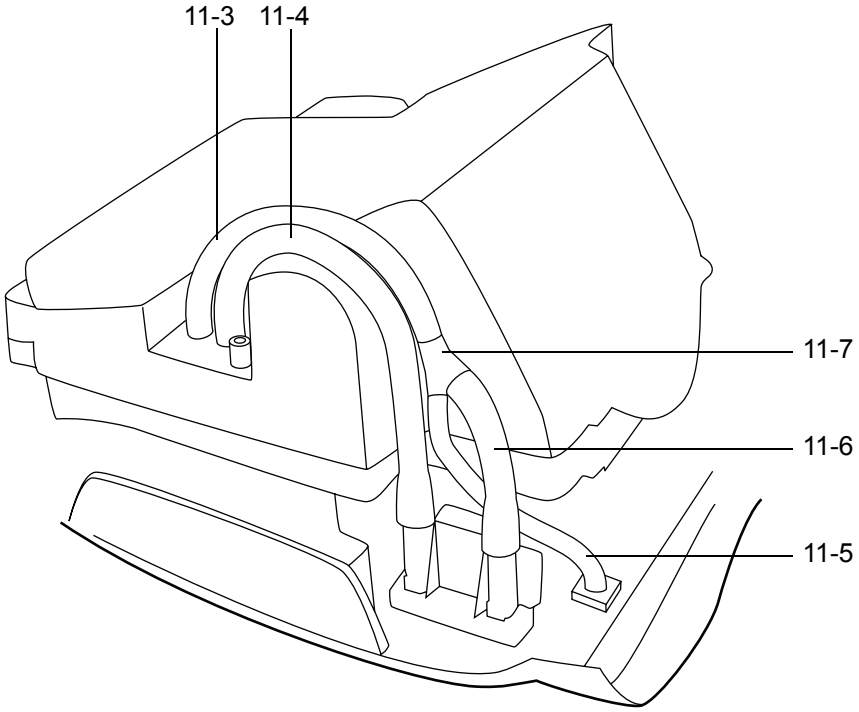
For definitions of the part numbers, refer to the parts list in section 3.5, "Parts List for the iSleep 20+/20i/22 and 25", on page 19.

3.3 Parts Drawing 3 – Front Casing, Circuit Board



For definitions of the part numbers, refer to the parts list in section 3.5, "Parts List for the iSleep 20+/20i/22 and 25", on page 19.

3.4 Tube Connections



For definitions of the part numbers, refer to the parts list in section 3.5, "Parts List for the iSleep 20+/20i/22 and 25", on page 19.

3.5 Parts List for the iSleep 20+/20i/22 and 25

The parts of the iSleep 20+/20i/22 and 25 are listed in the table below.

KIT NO.	DESCRIPTION	BREAS PART NO.	*AMOUNT*
1	**Air outlet patient assembly**	**003591**	*1*
2	**Contact cover - iSleep 20+/20i/22/25**	**003690**	*1*
3	**Battery CR2032 3V**	**002129**	*1*
4	**Friction pad**	**003692**	*1*
5	**Suspension noise box**	**004228**	*1*
6	**Screw kit – iSleep**	**004296**	
6-1	Screw STS-T30x8 FZB		*11*
7	**Case front kit - iSleep 20+**	**004297**	
7-1	Case front		*1*
7-2	Window “iSleep 20+“		*1*
7-3	Keypad		*1*
7-4	Air channel		*1*
7-5	Logotype “iSleep“		*1*
7-6	Insulation air channel		*1*
8	**Case front kit - iSleep 20i**	**004298**	
8-1	Case front		*1*
8-2	Window “iSleep 20i“		*1*
8-3	Keypad		*1*
8-4	Air channel		*1*
8-5	Logotype “iSleep“		*1*
8-6	Insulation air channel		*1*
9	**Case front kit - iSleep 22**	**004299**	
9-1	Case front		*1*
9-2	Window “iSleep 22“		*1*
9-3	Keypad		*1*
9-4	Air channel		*1*
9-5	Logotype “iSleep“		*1*
9-6	Insulation air channel		*1*
10	**Case front kit - iSleep 25**	**004738**	
10-1	Case front		*1*

KIT NO.	DESCRIPTION	BREAS PART NO.	*AMOUNT*
10-2	Window “iSleep 25“		*1*
10-3	Keypad		*1*
10-4	Air channel		*1*
10-5	Logotype “iSleep“		*1*
10-6	Insulation air channel		*1*
11	**Tube kit - iSleep 20+/20i/22/25**	**004300**	
11-1	Tube outlet		*1*
11-2	Tube inlet		*1*
11-3	Silicone tube - yellow long		*1*
11-4	Silicone tube - red		*1*
11-5	Silicone tube - pink or transparent		*1*
11-6	Silicone tube - yellow short		*1*
11-7	Y-connector		*1*
12	**Lock device kit - iSleep 20+/20i/22/25**	**004289**	
12-1	Lock device		*1*
12-2	Spring conical		*2*
13	**Blower assembly - iSleep 20+/20i/22/25**	**004227**	***1***
11-3	Silicone tube - yellow long		*1*
11-4	Silicone tube - red		*1*
11-5	Silicone tube - pink		*1*
11-6	Silicone tube - yellow short		*1*
11-7	Y-connector		*1*
14	**CPU board - iSleep 20+ (Language)**		
	PCB CPU iSleep 20+ SE	*004301*	*1*
	PCB CPU iSleep 20+ DE	*004302*	*1*
	PCB CPU iSleep 20+ FI	*004303*	*1*
	PCB CPU iSleep 20+ EN	*004304*	*1*
	PCB CPU iSleep 20+ NO	*004305*	*1*
	PCB CPU iSleep 20+ ES	*004306*	*1*
	PCB CPU iSleep 20+ IT	*004307*	*1*
	PCB CPU iSleep 20+ NL	*004308*	*1*
	PCB CPU iSleep 20+ DA	*004309*	*1*
	PCB CPU iSleep 20+ FR	*004310*	*1*

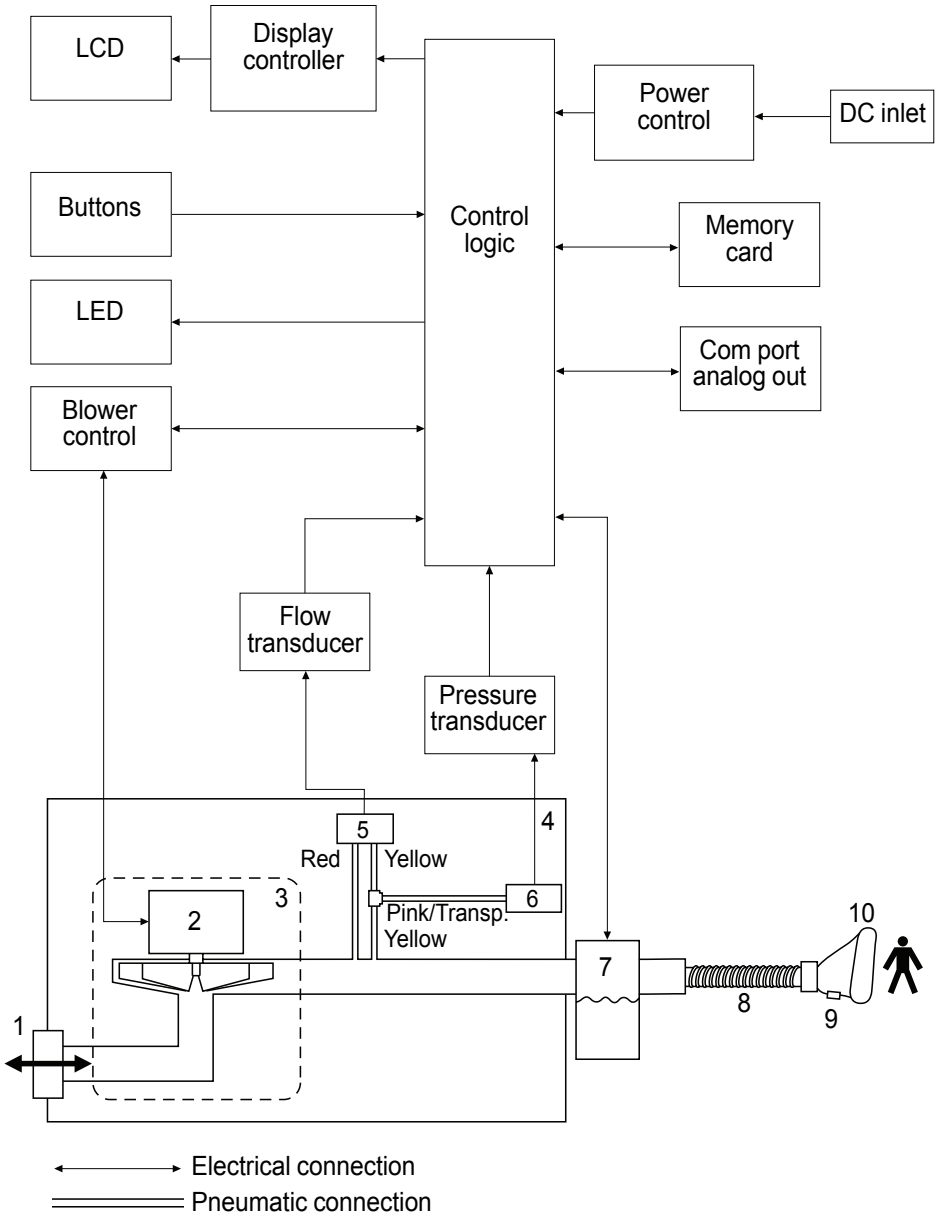
KIT NO.	DESCRIPTION	BREAS PART NO.	*AMOUNT*
	PCB CPU iSleep 20+ PT	*004311*	*1*
	PCB CPU iSleep 20+ EL	*004312*	*1*
	PCB CPU iSleep 20+ PL	*004313*	*1*
	PCB CPU iSleep 20+ JA	*004314*	*1*
	PCB CPU iSleep 20+ US	*004315*	*1*
	PCB CPU iSleep 20+ ZH	*004316*	*1*
15	**CPU board - iSleep 20i (Language)**		
	PCB CPU iSleep 20i SE	*004317*	*1*
	PCB CPU iSleep 20i DE	*004318*	*1*
	PCB CPU iSleep 20i FI	*004319*	*1*
	PCB CPU iSleep 20i EN	*004320*	*1*
	PCB CPU iSleep 20i NO	*004321*	*1*
	PCB CPU iSleep 20i ES	*004322*	*1*
	PCB CPU iSleep 20i IT	*004323*	*1*
	PCB CPU iSleep 20i NL	*004324*	*1*
	PCB CPU iSleep 20i DA	*004325*	*1*
	PCB CPU iSleep 20i FR	*004326*	*1*
	PCB CPU iSleep 20i PT	*004327*	*1*
	PCB CPU iSleep 20i EL	*004328*	*1*
	PCB CPU iSleep 20i PL	*004329*	*1*
	PCB CPU iSleep 20i JA	*004330*	*1*
	PCB CPU iSleep 20i US	*004331*	*1*
	PCB CPU iSleep 20i ZH	*004332*	*1*
16	**CPU board - iSleep 22 (Language)**		
	PCB CPU iSleep 22 SE	*004333*	*1*
	PCB CPU iSleep 22 DE	*004334*	*1*
	PCB CPU iSleep 22 FI	*004335*	*1*
	PCB CPU iSleep 22 EN	*004336*	*1*
	PCB CPU iSleep 22 NO	*004337*	*1*
	PCB CPU iSleep 22 ES	*004338*	*1*
	PCB CPU iSleep 22 IT	*004339*	*1*
	PCB CPU iSleep 22 NL	*004340*	*1*
	PCB CPU iSleep 22 DA	*004341*	*1*

KIT NO.	DESCRIPTION	BREAS PART NO.	*AMOUNT*
	PCB CPU iSleep 22 FR	*004342*	*1*
	PCB CPU iSleep 22 PT	*004343*	*1*
	PCB CPU iSleep 22 EL	*004344*	*1*
	PCB CPU iSleep 22 PL	*004345*	*1*
	PCB CPU iSleep 22 JA	*004346*	*1*
	PCB CPU iSleep 22 US	*004347*	*1*
	PCB CPU iSleep 22 ZH	*004348*	*1*
17	**CPU board - iSleep 25 (Language)**		
	PCB CPU iSleep 25 SE	*004739*	*1*
	PCB CPU iSleep 25 DE	*004740*	*1*
	PCB CPU iSleep 25 FI	*004741*	*1*
	PCB CPU iSleep 25 EN	*004742*	*1*
	PCB CPU iSleep 25 NO	*004743*	*1*
	PCB CPU iSleep 25 ES	*004744*	*1*
	PCB CPU iSleep 25 IT	*004745*	*1*
	PCB CPU iSleep 25 NL	*004746*	*1*
	PCB CPU iSleep 25 DA	*004747*	*1*
	PCB CPU iSleep 25 FR	*004748*	*1*
	PCB CPU iSleep 25 PT	*004749*	*1*
	PCB CPU iSleep 25 EL	*004750*	*1*
	PCB CPU iSleep 25 PL	*004751*	*1*
	PCB CPU iSleep 25 JA	*004752*	*1*
	PCB CPU iSleep 25 US	*004753*	*1*
	PCB CPU iSleep 25 ZH	*004754*	*1*

4 Functional Diagrams

This chapter contains a diagram of the pneumatic system of the CPAP/bi-level device and a block diagram of the iSleep 20+/20i/22/25's functions.

The functional block diagram below shows how the electronics and pneumatics are designed and how they are connected to the other components.



The table below describes the components of the functional diagram.

NO.	DESCRIPTION
1	Air inlet filter
2	Blower
3	Silencer box
4	iSleep 20+/20i/22/25 casing
5	Flow sensor
6	Pressure sensor
7	Humidifier (optional)
8	Patient tube
9	Leak holes
10	Mask

4.1 Filtering/Smoothing Techniques

FUNCTION	TECHNIQUE DESCRIPTION
Pressure	Low pass average time constant 16 ms
Inspiration trigger (iSleep 22/25 only)	Differential flow resolution 4 ms
Expiration trigger (iSleep 22/25 only)	Flow low pass filtering with level sensing

4.2 iSleep 20+/20i/22/25 Measuring and Display Devices

DEVICE	PURPOSE	TYPE	RANGE	RESOLUTION	ACCURACY	SENSING POSITION
Pressure sensing	Regulate pressure	Differential to ambient	-10 to +60 cmH_2O	0.1 cmH_2O	±0.1% FSS	Air outlet of iSleep
Flow sensing	Regulate pressure	Mass flow	0 to 300l/min	1l/min	±1l/min	Air outlet of iSleep
Pressure display	Indicate patient pressure	Graphic LCD	0 to 20 cmH_2O	0.1 cmH_2O	±2% of full scale and ±4% of actual reading	Air outlet of iSleep

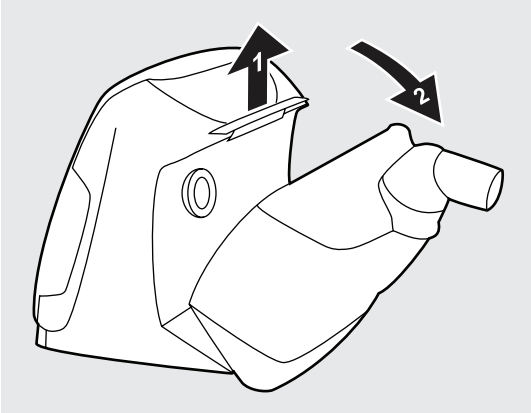
5 Opening the iSleep 20+/20i/22/25 and Replacing the Main Components

Make sure to disconnect the power supply before removing the casing of the CPAP/bi-level device.

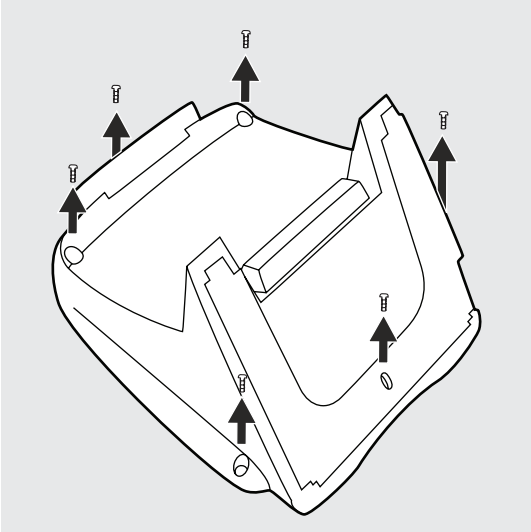
5.1 Opening the iSleep 20+/20i/22/25

- Make sure that the iSleep 20+/20i/22/25 is placed on a non-scratching surface.
- Before closing the iSleep 20+/20i/22/25, perform an internal inspection, see "Internal Inspection" on page 10.
- Make sure that the tubes are not pinched or kinked when closing the iSleep 20+/20i/22/25.
- Always perform an electrical safety test after reassembling the iSleep 20+/20i/22/25, see "Electrical Safety Precautions" on page 14.
- Always perform a complete function test after reassembling the iSleep 20+/20i/22/25, see "Complete Function Test" on page 11.

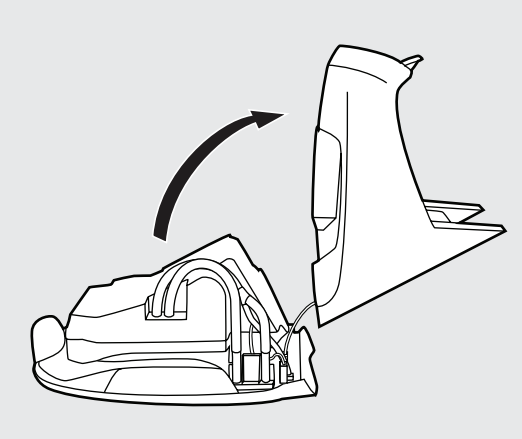
1 Remove the rear lid or the HA01 humidifier (if used).



2 Remove the six screws for the casing.

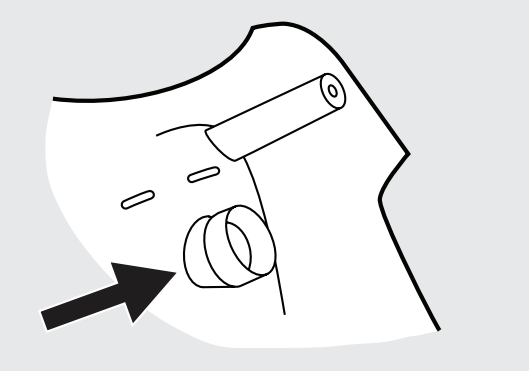


3 Lift the back casing straight up and tilt it backwards onto the table.



4 Reassemble in reverse order.
Make sure that the inlet and outlet tubes are properly fitted.

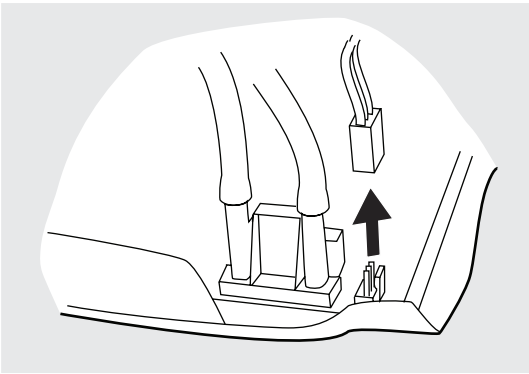
- The outlet tube should be pointing slightly upwards when fitted to the back casing.



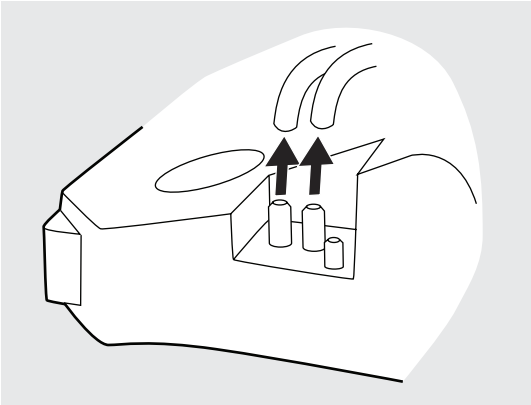
5.2 Replacing the Complete Blower Assembly

1 Open the iSleep 20+/20i/22/25 as in section 5.1.

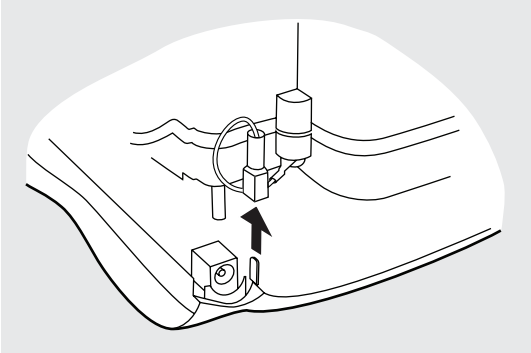
2 Disconnect the cabling for the BLDC motor control.



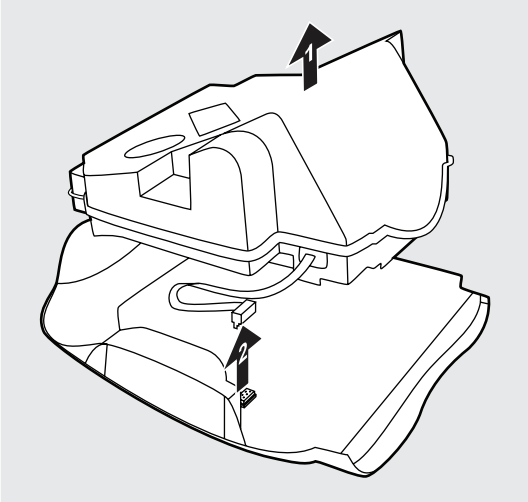
3 Disconnect the tubings.



4 Disconnect the ground cable.



5 Lift the blower assembly and disconnect the blower cabling.



6 Reassemble in reverse order.

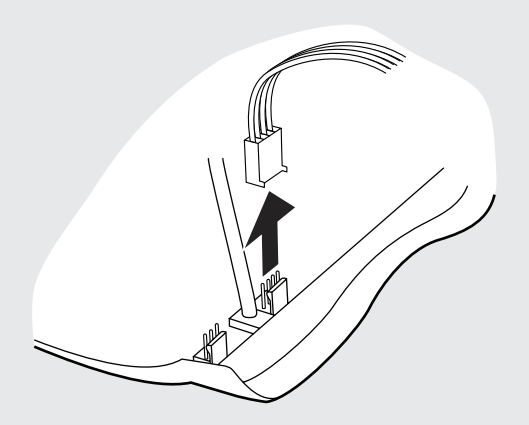
5.3 Replace the Circuit Board

The iSleep 20+/20i/22/25 serial number must be programmed into the new circuit board.

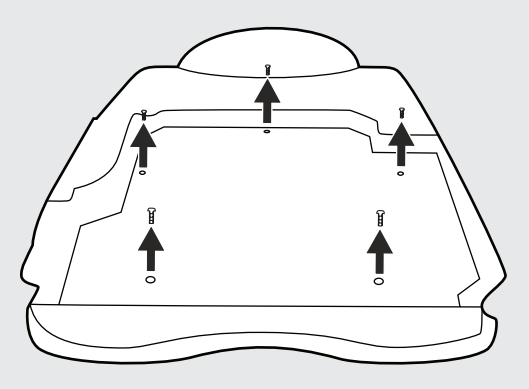
You need the iSleep/Vivo Service Software to program the circuit board with the correct serial number after replacement.

1 Open the iSleep 20+/20i/22/25 and disconnect the blower assembly as in section 5.2.

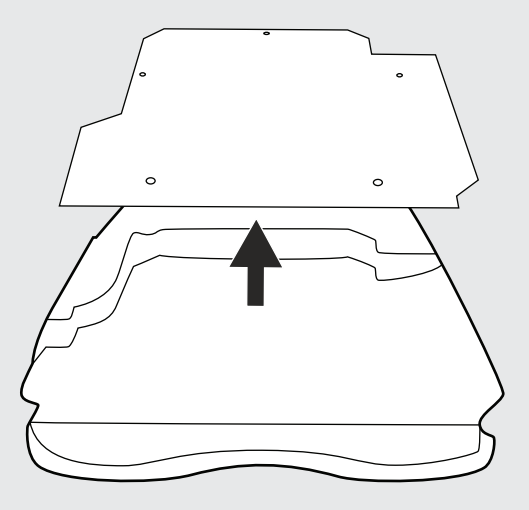
2 Disconnect the cabling for the humidifier.



3 Remove the five screws for the circuit board.



4 Lift the circuit board by it's edges straight up.



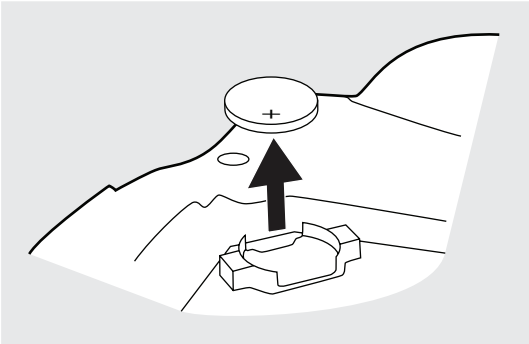
5 Reassemble in reverse order.

Remove the tubings from the old circuit board and attach them to the new one.

5.4 Replace the Clock Battery

1 Open the iSleep 20+/20i/22/25 as in section 5.1 and move the blower assembly from the circuit board so you can access the clock battery.

2 Remove the clock battery by pulling it straight up. Press a new clock battery into place.



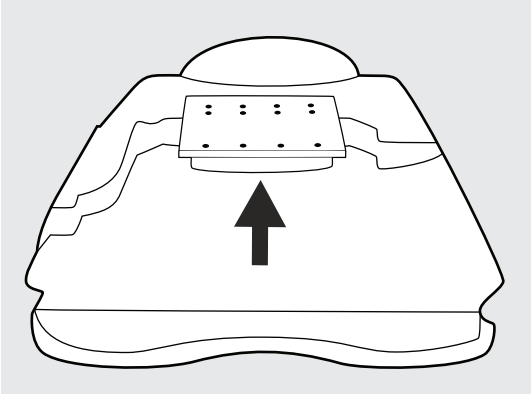
Make sure that the new battery is not handled with bare hands.

3 Reassemble in reverse order.

5.5 Replacing the Keypad

1 Remove the circuit board as in section 5.3.

2 Remove the keypad.



3 Reassemble in reverse order.

6 Upgrade and Calibration

6.1 Firmware Upgrade

To upgrade the iSleep 20+/20i/22/25 firmware you need the "Firmware Upgrade Tool iSleep/Vivo" available for download from Breas Extranet. Contact Breas technical support for more information.

6.2 Pressure and Flow Calibration

To calibrate the iSleep 20+/20i/22/25 you need the "iSleep/Vivo Service Software" available for download from Breas Extranet. Contact Breas technical support for more information.

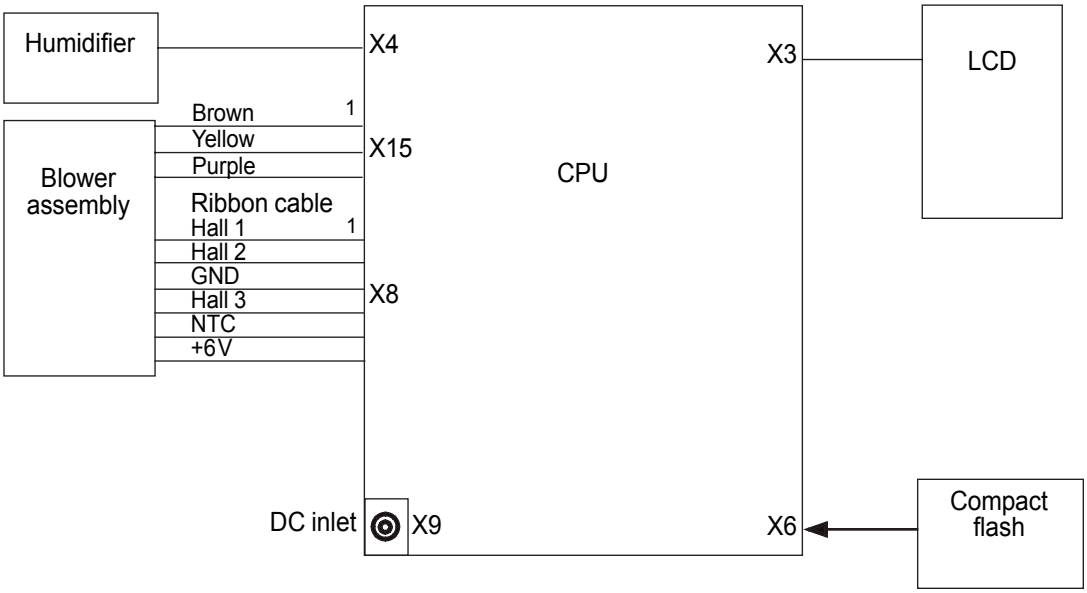
7 Electronics

Always perform a complete function test if you have opened the iSleep 20+/20i/22/25.

The electronics, optics, mechanics, and pneumatics of the iSleep 20+/20i/22/25 are integrated. To fully understand the electronics of the iSleep 20+/20i/22/25, you must know how to use the CPAP/bi-level device, study the pneumatic diagram and acquaint yourself with the mechanical construction.

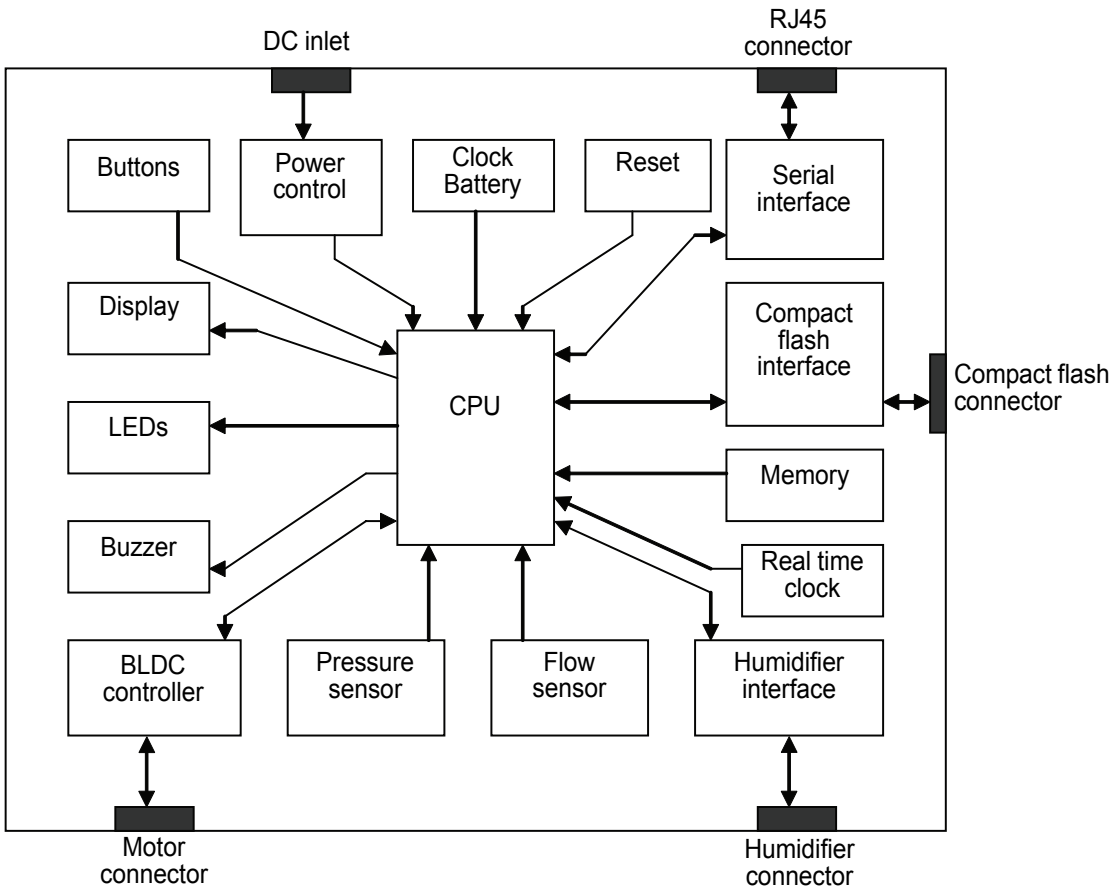
7.1 Main Cabling Diagram of the iSleep 20+/20i/22/25

The diagram below illustrates the main cabling of the iSleep 20+/20i/22/25.



7.2 Circuit Board Description

The diagram below is an overview of the circuit board



Power Control

There is one power input (+24V DC). The circuit board contains voltage regulators for 3.3V, 5V, 8V and 12V.

Clock Battery

A battery is used to keep the real time clock alive when the iSleep 20+/20i/22/25 is unpowered.

CPU (Central Processing Unit)

The processing core of the main unit is a M16C62P Microcontroller.

The main processor has a supply voltage of 3.3V (data side) and 5V (signal side) and is not operating when the iSleep is unpowered.

Display

The display used is a graphic type and have a visible area of approximately 60x40mm.

Buzzer

The buzzer is triggered by software or hardware.

Brushless DC (BLDC) Motor Controller

The BLDC amplifier is based on a three-phase inverter controlled by a MC33035 motor control circuit. The processor regulates the speed with a 0-5 V analogue signal into the MC33035P. The processor can also brake the BLDC motor via the control circuit. To determine if the fan is running, the processor senses one hall element from the BLDC motor. The control circuit also has a built-in over current protection.

Pressure Sensor

The iSleep 20+/20i/22/25 is equipped with a pressure sensor. The processor supervises the actual pressure and have the ability to regulate the speed of the motor to attain a correct pressure.

Flow Sensor

The flow sensor is used for air flow measurements.

Humidifier Interface

The iSleep 20+/20i/22/25 can be equipped with an integrated humidifier, HA01.

The HA01 humidifier consumes approximately 40 W when attached to the iSleep 20+/20i/22/25.

The power to the HA01 humidifier is controlled from the main CPU via a transistor.

The other two signals in the interface beside power and ground are an analogue temperature signal from the HA01 humidifier and a control signal to the HA01 humidifier.

Compact Flash Memory Interface

The main processor can transfer the data log from the memory to the compact flash memory.

Serial Interface

To communicate with a PC, the iSleep 20+/20i/22/25 uses a RS232 interface.

8 Fault Tracing

Always perform a Complete Function Test if you have opened the iSleep 20+/20i/22/25.

This chapter contains a fault-tracing table and a table of error codes to use when troubleshooting the iSleep 20+/20i/22/25.

8.1 Fault Tracing Table

If the iSleep 20+/20i/22/25 does not work properly try to identify the problem in the table below. Check the possible causes and carry out the suggested remedial actions.

SYMPTOM	POSSIBLE CAUSE	REMEDIAL ACTION	SEE REF.
The iSleep 20+/ 20i/22/25 does not start	The power cord is not properly connected.	Connect the power cord.	Clinician's manual
	The DC fuse on the circuit board has blown.	Replace the circuit board and check the power supply.	5.3, p.28
	The power supply is not 24V DC.	Check the power transformer.	
	The external battery is discharged.	Charge the external battery.	
	The external battery cable is not properly connected or is faulty.	**1** Connect the cable. **2** Measure the voltage. **3** Replace the cable if faulty.	
	Battery polarity faulty. May be the case if fuse blows immediately after connecting to external battery cable.	Check polarity.	
The iSleep 20+/ 20i/22/25 does not give the adequate pressure.	External leaks from patient circuit or nasal mask.	Check the tubes, connectors and mask for leaks.	2.3, p.9
	Internal leaks from tubes, humidifier or air channels.	Check the tubes, air channels and the humidifier.	2.4, p.10
	The air inlet is blocked.	Check the filter and air channels.	
Pressure indicator shows no pressure reading.	The internal supply tube is blocked or loose.	Check the tubes.	2.4, p.10
	The circuit board is faulty.	Replace the circuit board.	5.3, p.28
The clock resets when having disconnected the power supply.	The clock battery is discharged.	Replace the clock battery.	5.4, p.29

8.2 Function Failure Error Codes

8.2.1 Reading the Error Codes

When an internal function failure occurs an internal error code will be stored in the iSleep 20+/20i/22/25 error log and a message will be shown on the display.

You need the iSleep/Vivo Service Software to access the error log.

8.2.2 Error Code Table

The table below lists each error code and the corresponding text that is shown on the LCD display. The problem is explained together with the action that is necessary to correct the problem.

If more than one action is listed, the actions should be performed in the order in which they are listed. For example: if action no. 1 does not solve the problem you should continue with action no. 2, and so on.

See "Opening the iSleep 20+/20i/22/25 and Replacing the Main Components" on page 25 for information about how to replace the circuit board.

Error code	Text on LCD Display	Problem	Action
5	Error code: 5 Internal function failure. Contact your provider.	Pressure sensor fail.	**1** Restart the iSleep 20+/20i/22/25 by disconnecting and reconnecting the power supply. **2** Perform an internal inspection. **3** Replace the circuit board or send the iSleep 20+/20i/22/25 for service.
6	Error code: 6 Internal function failure. Contact your provider.	Flow sensor fail.	**1** Restart the iSleep 20+/20i/22/25 by disconnecting and reconnecting the power supply. **2** Perform an internal inspection. **3** Replace the circuit board or send the iSleep 20+/20i/22/25 for service.
12	Error code: 12 Internal function failure. Contact your provider.	Motor current is too high.	**1** Restart the iSleep 20+/20i/22/25 by disconnecting and reconnecting the power supply. **2** Perform an internal inspection. **3** Replace the blower assembly. **4** Replace the circuit board or send the iSleep 20+/20i/22/25 for service.

Error code	Text on LCD Display	Problem	Action
15	Error code: 15 Internal function failure. Contact your provider.	Saved time for the latest power down is corrupt.	**1** Restart the iSleep 20+/20i/22/25 by disconnecting and reconnecting the power supply. **2** Replace the clock battery. **3** Replace the circuit board or send the iSleep 20+/20i/22/25 for service.
17	Error code: 17 Internal function failure. Contact your provider.	CPU voltage is out of range.	**1** Restart the iSleep 20+/20i/22/25 by disconnecting and reconnecting the power supply. **2** Replace the circuit board or send the iSleep 20+/20i/22/25 for service.
32	Error code: 32 Internal function failure. Contact your provider.	Parameters are corrupt. Settings set to default values.	**1** Restart the iSleep 20+/20i/22/25 by disconnecting and reconnecting the power supply. Restore the patient settings. **2** Replace the circuit board or send the iSleep 20+/20i/22/25 for service.
35	Error code: 35 High temperature. Cool the device and restart.	Pressure sensor temperature is too high.	**1** Disconnect the iSleep 20+/20i/22/25 from the power supply, let the device cool off and restart. **2** Check the ambient temperature. **3** Replace the circuit board or send the iSleep 20+/20i/22/25 for service.
36	Error code: 36 Internal function failure. Contact your provider.	Motor temperature is too high.	**1** Disconnect the iSleep 20+/20i/22/25 from the power supply, let the device cool off and restart. **2** Check the ambient temperature. **3** Perform an internal inspection. **4** Replace the blower assembly. **5** Replace the circuit board or send the iSleep 20+/20i/22/25 for service.

Error code	Text on LCD Display	Problem	Action
38	Error code: 38 Internal function failure. Contact your provider.	Settings are corrupt. Settings set to default values.	**1** Restart the iSleep 20+/20i/22/25 by disconnecting and reconnecting the power supply. Restore the patient settings. **2** Replace the circuit board or send the iSleep 20+/20i/22/25 for service.
64	Error code: 64 Check power supplies.	Supply voltage is out of range.	**1** Check power supply. **2** Replace the circuit board or send the iSleep 20+/20i/22/25 for service.
66	Error code: 66 Internal function failure. Contact your provider.	High Pressure.	**1** Restart the iSleep 20+/20i/22/25 by disconnecting and reconnecting the power supply. Restore the patient settings. **2** Replace the circuit board or send the iSleep 20+/20i/22/25 for service.
130	Error code: 130 Stored settings corrupt. Returned to default settings.	Stored settings are corrupt. Settings set to default values.	**1** Restart the iSleep 20+/20i/22/25 by disconnecting and reconnecting the power supply. Restore the patient settings. **2** Replace the circuit board or send the iSleep 20+/20i/22/25 for service.
131	Error code: 131 Humidifier disconnected.	The humidifier is not properly connected.	**1** Check the HA01 humidifier. **2** Replace the HA01 humidifier. **3** Replace the circuit board or send the iSleep 20+/20i/22/25 for service.
132	High leakage during session. Check mask.	High leakage.	**1** Check patient circuit and mask. **2** Perform an internal inspection. **3** Replace the circuit board or send the iSleep 20+/20i/22/25 for service.
133	Error code: 133 Low humidifier temperature. Check humidifier.	The humidifier is not heating.	**1** Replace the HA01 humidifier. **2** Perform an internal inspection. **3** Replace the circuit board or send the iSleep 20+/20i/22/25 for service.

Error code	Text on LCD Display	Problem	Action
134	Error code: 134 High humidifier temperature. Check humidifier.	Humidifier temperature is too high.	Replace the HA01 humidifier.

9 Appendices

9.1 Emission and Immunity Declaration

According to IEC 60601-1-2(2001) + A1(2004).

9.1.1 Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The iSleep 20+/20i/22/25 are intended for use in the electromagnetic environment specified below. The customer or the user of the iSleep 20+/20i/22/25 should assure that it is used in such an environment.

Portable and mobile RF (radio frequency) communications equipment should not be used no closer to any part of the iSleep 20+/20i/22/25, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	RECOMMENDED SEPARATION DISTANCE
Conducted RF IEC 61000-4-6	3 V_{rms} 150 kHz to 80 MHz	10 V	d= 0.27*√P m
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	10 V/m	d= 0.27*√P m at 80 MHz to 800 MHz d= 0.54*√P m at 800 MHz to 2.5 GHz **Equation description:** P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with this symbol.

Notes

- At 80 MHz and 800 MHz, the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the iSleep 20+/20i/22/25 is used exceeds the applicable RF compliance level above, the iSleep 20+/20i/22/25 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the
iSleep 20+/20i/22/25.

b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

9.1.2 Guidance and Manufacturer's Declaration – Electromagnetic Emission

The iSleep 20+/20i/22/25 are intended for use in the electromagnetic environment specified below. The customer or the user of the iSleep 20+/20i/22/25 should assure that it is used in such an environment.

EMISSIONS TEST	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT – GUIDANCE
RF emissions CISPR 11	Group 1	The iSleep 20+/20i/22/25 use RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The iSleep 20+/20i/22/25 are suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emission IEC 61000-3-3	Complies	

9.1.3 Recommended separation distances between portable and mobile RF communications equipment and the iSleep 20+/20i/22/25

The iSleep 20+/20i/22/25 are intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the iSleep 20+/20i/22/25 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the iSleep 20+/20i/22/25 as recommended below, according to the maximum output power of the communications equipment.

RATED MAXIMUM OUTPUT POWER OF TRANSMITTER (W)	SEPARATION DISTANCE ACCORDING TO THE FREQUENCY OF TRANSMITTER (M)		
	150 kHz to 80 MHz d= 0.27*√P m	**80 MHz to 800 MHz d= 0.27*√P m**	**800 MHz to 2.5 GHz d= 0.54*√P m**
0.01	0.03	0.03	0.05
0.1	0.08	0.08	0.17
1	0.27	0.27	0.54
10	0.85	0.85	1.7
100	2.7	2.7	5.4

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Notes

- At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

9.2 CPAP Data

The values have been produced during a test where the iSleep 20+/20i/22/25 have been attached to a 0.5 litre test lung simulating a sinusoidal breathing pattern with 20 breaths/minute.

9.2.1 iSleep 20+

Average Value and Variation of Air Pressure at the Patient Air Outlet

VOLUME (L)	PRESSURE P (cmH_2O)	BREATHING RATE F (min^{-1})	AVERAGE VALUE (cmH_2O)	VARIATION (cmH_2O)
0.5	$^1/_3 p_{max} = 6.5$	20	7.20	0.55
0.5	$^2/_3 p_{max} = 13$	20	14.07	0.58
0.5	$P_{max} = 20.0$	20	21.23	0.81

9.2.2 iSleep 20i

Average Value and Variation of Air Pressure at the Patient Air Outlet

VOLUME (L)	PRESSURE P (cmH_2O)	BREATHING RATE F (min^{-1})	AVERAGE VALUE (cmH_2O)	VARIATION (cmH_2O)
0.5	$^1/_3 p_{max} = 6.5$	20	6.50	0.50
0.5	$^2/_3 p_{max} = 13$	20	13.02	0.49
0.5	$P_{max} = 20.0$	20	19.93	0.89

9.2.3 iSleep 22

Average Value and Variation of Air Pressure at the Patient Air Outlet

VOLUME (L)	PRESSURE P (cmH_2O)	BREATHING RATE F (min^{-1})	AVERAGE VALUE (cmH_2O)	VARIATION (cmH_2O)
0.5	$^1/_3 p_{max} = 6.5$	20	6.77	0.50
0.5	$^2/_3 p_{max} = 13$	20	13.32	0.48
0.5	$P_{max} = 20.0$	20	20.40	0.64

9.2.4 iSleep 25

Average Value and Variation of Air Pressure at the Patient Air Outlet

VOLUME (L)	PRESSURE P (cmH_2O)	BREATHING RATE F (min^{-1})	AVERAGE VALUE (cmH_2O)	VARIATION (cmH_2O)
0.5	$^1/_3 p_{max} = 6.5$	20	6.55	0.50
0.5	$^2/_3 p_{max} = 13$	20	12.80	0.69
0.5	$P_{max} = 20$	20	19.70	0.86

9.3 Maximum Limited Pressure during Single Fault Condition

DEVICE		VALUE
iSleep 20+/20i/22		30 cmH_2O
iSleep 25	CPAP Mode	30 cmH_2O
	Bi-level Mode	40 cmH_2O

9.4 Service Record iSleep 20+/20i/22/25

Use a photocopy of this service record for the inspections described in "Service Instructions" on page 6. Use the next page for comments and notes.

Service record no._____

Model:..... **Serial no.** ..... **Inventory no.** .....

Accessories: .....

Delivery date: ..... Total operating hours: .....

Service started: ..... Signature: .....

Service completed: ..... Signature: .....

Product returned: ..... Signature: .....

General	**See instruction ref.**	**Check OK**
Open a new service record	2.2.1, p.8	.....
Identify the CPAP/bi-level device	2.2.1	.....
Note the number of total operating hours	2.2.1	.....
Check all markings	2.2.2	.....
Check information from user	2.2.3	.....
Check validity of documentation	2.2.4	.....
External Checks		
Inspect for external damage and wear	2.3.1, p.9	.....
Check the HA01 humidifier (if used)	2.3.2	.....
Check power connection	2.3.3	.....
Inspect patient circuit	2.3.4	.....
Inspect the CPAP/bi-level device accessories	2.3.5	.....
Change/wash the patient filters	2.3.6	.....
Perform minimum function check	2.3.7	.....
Internal Checks (when required)		
Clean the inside of the CPAP/bi-level device	2.4.1, p.10	.....
Check cabling	2.4.2	.....
Check fastening of components	2.4.3	.....
Check the power supply	2.4.4	.....
Reassemble the casing	2.4.5	.....
Complete Function Check		
Check the pressure	2.5.1, p.11	.....
Check the mask-off detection	2.5.2	.....
Check the snooze function	2.5.3	.....
Check the leakage indication	2.5.4	.....
Check the power fail indication	2.5.5	.....
Check the Backup Rate (iSleep 22/25 only)	2.5.6	.....
Check the inspiratory trigger (iSleep 22/25 only)	2.5.7	.....
Adjust settings for patient	2.5.8	.....

9.5 Returning Products to Breas

You may need to return the CPAP/bi-level device, components or accessories to Breas Medical AB for service, warranty, upgrade or repair. In this case, follow the instructions below to ensure that the correct action is taken to avoid unnecessary delays.

1 Pack the product in its original packing. If this is not available, pack the product in packaging suitable for the transportation to Breas Medical AB.

2 Take a photocopy of the delivery report on page 46.

3 Fill out the delivery report and pack it together with the product to be returned.

Product damage caused by poor packaging or during transportation is not covered by the factory warranty.

9.6 Product Return Form – Breas iSleep 20+/20i/22/25

Breas ref. no.:.....

Customer information

Customer name:.....

Address: .....

.....

Phone:.....

Reference person: ..... **Customer ref. no.:**.....

Product information

Model: ..... **Serial no.:**..... **Total operating hours:**.....

Error – Complaint – Accessories

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